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REMARKS

In the final Office Action dated May 10, 2006, the Examiner allowed claims 49-51. Applicant thanks the Examiner for the allowance of these claims.

Additionally, based on the Examiner's suggestion in the final Office Action, Applicant has amended independent Claims 26 and 46 to positively recite the U-shape of the trap, by adding the limitation, the trap having a low region that is lower than the inlet valve and the outlet valve. Claim 33 has been amended to correct a typographical error.

Applicant submitted a draft of this response and amendments to the Examiner, Nathan Bowers on August 10, 2006. During a telephone interview with the Examiner on August 10, 2006, the Examiner stated that the amended claims are patentable over the references cited in the final Office Action. At the same time, the Examiner also cited two new references; Tran (US 5,460,054) and Stokley et al (US 4,167,117.) During a follow-up telephone interview to discuss these references with the Examiner on August 17, 2006, the Examiner stated that the amended claims are also patentable over the additional references, as they are not relevant to bioreactors, aseptic sampling of biofluids, and directing wash fluids through a bioreactor.

The Examiner had rejected claims 26-29, 36, and 37 under 35 U.S.C. 103(a) as being unpatentable over Newberg (U.S. Patent Number 5,296,197) in view of Witte (U.S. Patent Number 5,948,998); Claims 26-29, 36, 37, and 43-45 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte and Rutherford (US 5948998); claims 30-32 and 39 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte as applied to claim 27 and in further in view of Carney (U.S. 5,771,917); claim 38 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte as applied to claim 27, in further view of Merten (U.S. 6,689,621); claim 40 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte and Carney as applied to claim 39, and further in view of Merten (U.S. 6,689,621); claims 41 and 42 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte, Carney, and Merten as applied to claim 40, and further in view of North, Jr. (U.S. 5,395,588); claims 43-45 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte as applied to claim 26, and further in view of Gerard (U.S. 20020170364); and claim 46 under 35

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U.S.C. 103(a) as being unpatentable over Newberg in view of Witte, Carney, Merton, and North, Jr.

In order to reject a claim under 35 U.S.C. §103(a), the Office Action must first establish a *prima facie* case of obviousness. Establishing a *prima facie* case of obviousness requires that: (i) there must be some suggestion or motivation, either in the reference or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (ii) there must be a reasonable expectation of success; and (iii) the prior art reference must teach or suggest all of the claim limitations. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Though Applicant disagrees with the rejections of the defendant claims, only independent claims and specific references pertaining to those independent claims will be discussed.

The Examiner rejected claims 26-29, 36, and 37 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte. Newberg describes an apparatus for withdrawing a sample from a vessel or conduit, where the apparatus includes a main body with an inlet passage and a drain passage. As described by the Examiner, a biofluid sample is collected by opening an inlet valve at a biofluid source site. The sample can then be directed to a biofluid process site by opening an outlet valve coupled to a process site. A waste valve is coupled to a sampling conduit and the waste valve is closed in order to move the sample to the process site. Steam, pure dry air or a wash medium can be provided through the inlet passage to cleanse the apparatus.

Witte discloses a sampling device for taking sterile samples of a fluid from a fermentor or bio-reactor. The device includes a holder in fluid communication with the fermentor for removably connecting sample collecting containers. An adapter is removably connected to the holder for steam sterilization of the holder between collection of successive samples.

The Examiner stated that Newberg does not disclose a trap located at the sampling conduit and fluidly connected to the waste valve. The Examiner also stated that Witte discloses a trap that is in connection with the sampling conduit and in fluid communication with a waste site. For reference, Examiner refers to Figure 1:36. Witte explicitly describes the trap as a steam trap. (Col. 1, lines 36-64). The purpose of the steam trap as described, is to collect steam during sterilization of the apparatus.

Claim 26 was amended per the Examiner's suggestion to add the limitation the trap having a region that is lower than the inlet valve and the outlet valve... As disclosed by Witte in Figure 1,

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the steam trap does not have a region that is lower than the inlet valve and outlet valve, and the waste valve is not coupled to the low region of the trap. Firstly, the waste valve as disclosed by Witte, is located above the steam trap as shown in Fig. 1. Also, the steam trap is at an equivalent height to the inlet valve or source site 14. Additionally, in the last response, Applicant had amended claim 26 to state that the trap is a portion of the sampling conduit, noting that the sample flows through the trap. The Examiner had not addressed this argument with respect to Witte. Witte does not disclose the steam trap being in the flow path of the sample as is shown in Applicant's Figures 7A-7C. Witte's waste mechanism discloses a "catch vessel" of sorts, while the Applicant's trap and waste valve is an automatic catch, due to the trap having a low region that is lower than the inlet and the outlet valves, and the waste valve being coupled to that low region.

Rejected defendant claims 27-29, 30-32, 36, 37, 38, 39, 40, 41, 42, and claims 43-45 are all defendant on base claim 26, and therefore include all of the limitations of the amended base claim. For the reasons stated regarding the 103(a) rejection of claim 26, the combination of Newberg and Witte, along with any other reference cited by Examiner, did not teach or suggest all of the claim limitations of defendant claims 27-29, 30-32, 36, 37, 38, 39, 40, 41, 42, and claims 43-45.

The Examiner had rejected claims 26-29, 36, 37, and 43-45 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte and a new reference, Rutherford. For the reasons described in the 103(a) rejection discussion of claim 26 above, the combination of Newberg and Witte failed to teach or suggest all of the claim limitations of independent claim 26, and thus the claims defendant on 26. Rutherford describes an improved drain trap assembly for use in the plumbing industry, which is designed to allow for disposal of sediment. Rutherford's drain trap assembly is geared toward plumbing, and is not a device for "aseptically sampling a biofluid." Rutherford, in Figure 1, discloses a drain trap attached to a sink 11 and a sewer line 12. (Rutherford, Col. II, lines 17-39.) Because Rutherford's drain trap is a plumbing apparatus, which does not aseptically sample a biofluid, it is non-analogous to the Applicant's disclosure. Even if Rutherford's waste mechanism, including waste valve 21 and waste site 22 was combined with Newberg and Witte, it would replace Witte's steam trap and waste valve, and would thus, still not have a low region that is lower than the inlet valve and outlet valve.

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Therefore, the combination of Newberg, Witte, and Rutherford, along with any other reference cited by Examiner, did not teach or suggest all of the claim limitations of claim 26 and thus of any claim dependant on claim 26.

The Examiner further rejected claim 46 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte, Carney, Merten, North Jr, and Rutherford. For the reasons cited above, the combination of Newberg, Witte, and Rutherford, along with any other reference cited by Examiner, did not teach or suggest all of the claim limitations of claim 46.

Also, the Examiner rejected claims 43-45 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte as applied to claim 26, and further in view of Gerard (U.S. 20020170364. Gerard describes a sampling container for taking samples from a tank containing a flammable liquefied gas. Gerard does not disclose a device or method for "aseptically sampling a biofluid." Gerard's device is therefore, non-analogous to the Applicant's disclosure. For the same reasons as cited in arguments above, the combination of Newberg, Witte, and Gerard did not teach or suggest all of the limitations of claim 26, or dependant claims 43-45 for the same reasons.

Accordingly, Applicants submitted that claims 26, 27-29, 30-32, 36, 37, 38, 39, 40, 41, 42, claims 43-45, and claim 46 are not obvious in view of the prior art because the Office Action had not established a prima facie case of obviousness for these claims. Applicants respectfully request that Examiner withdraw the §103(a) rejection of these amended claims, and allow all pending claims.

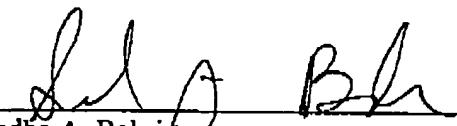
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CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that an additional telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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